

REMARKS

First of all applicants wish to thank the Examiner for the courtesies extended to the undersigned attorney during a telephonic Examiner's interview conducted on October 10, 2008. The Examiner's Interview Summary accurately reflects the content of that discussion. During that interview applicants discussed the teachings of the prior art reference, US patent No: 6,270,347 (the '347 patent) and requested further clarification regarding the claim rejections. The Examiner noted that the objection to claim 37 should have been based solely on 35 USC 112 rather than 35 USC 103. In particular, the Examiner noted the indefiniteness of claim 37 due to the use of "comprising" language in conjunction with "consisting of" language in that claim. Accordingly, applicants agreed to submit claim amendments to address the noted objection under 35 USC 112, second paragraph. Applicants also discussed the cited '347 patent, and noted that it was directed to nanostructured ceramics and composites thereof, but failed to disclose nanostructured polymeric materials. Applicants stated their belief that the claims specifically require a polymeric material as a component of the composition wherein the polymeric material displays nano-sized surface features. Thus applicants argued that while the '347 patent disclosed compositions comprising polymeric materials, the patent failed to teach or suggest that such additional polymeric materials could themselves have nano-sized surface features.

Applicants have amended the claims in an effort to clarify the scope of the present invention. In particular independent claims 1, 2 and 38 have been amended to specifically recite that the implant comprises a polymeric component, wherein the polymeric component has nano-sized features displayed on its surface. Thus the claimed compositions require the presence of a polymeric material that displays nano-sized surface features (i.e., the polymer is "nanotextured") as a specific element of the composition. Furthermore claim 37 has been amended to remove the improper "comprising" language contained within the claim.

Claims 1-5, 7-19 and 33-42 stand rejected under 35 USC §103 as being unpatentable over Webster (US Patent No. 6,270,347). Applicants respectfully traverse this rejection.

As applicants emphasized during the telephonic interview, the Webster '347 patent is limited to compositions comprising nanostructured ceramics for oethopaedic/dental applications. Applicants respectfully submit that throughout the specification, the '347 patent repeatedly makes reference to "nanostructured" and "nanophase" materials, but in every instance the word nanostructured is followed by ceramic. Accordingly, the specification makes clear that the only materials contemplated by the '347 patent as being modified to

display a nanostructured surface are ceramic materials. As noted by the Examiner, the '347 patent also discloses composite materials that comprise a nanostructured ceramic and "one or more natural or synthetic polymers, other than a peptide, in addition to the nanophase materials" (see column 5, lines 31-35; emphasis added). Applicants respectfully submit that the '347 patent clearly indicates that the nanotextured ceramics are the active agent, and that additional known conventional materials (including polymeric materials) could be combined with the novel nanostructured ceramic material of the invention. The reference is simply devoid of any teaching or suggestion that these supplemental materials could be modified to display nano-sized features. Accordingly, applicants respectfully submit that an objective reading of the '347 patent indicates the patent's teaching is limited to nanostructured ceramics and fails to teach or suggest a composition that comprises a nanotextured polymeric material as claimed in the present invention.

Furthermore, the '347 reference teaches a procedure for forming nanostructured ceramic materials that is not applicable for forming other nanostructured materials. More particularly, the preparation of the nano-grained ceramic materials of the '347 patent is conducted by forming precipitates of ceramic materials using controlled reactions. There is no disclosure relating how to prepare polymeric materials that display nano-textured surfaces. Accordingly, not only does the '347 patent fail to teach or suggest the desirability of a composition comprising nano-structured polymeric materials, the reference is devoid of any guidance of how to prepare such polymeric materials that display nano-sized surface features.

Furthermore, applicants note that claims 1 and 37 of the present application also require the polymeric surface to display a surface roughness of 50 nm or greater. Again the Webster '347 patent is devoid of any teaching or suggestion with regards to the preparation, or the desirability, of a polymeric material that displays a surface roughness of 50 nm or greater.

Applicants also respectfully submit that even if one of ordinary skill in the art could conceive of a method of preparing a composition comprising a nano-structured polymeric material, the prior art (including the '347 patent) failed to provide any motivation for doing so. First of all, one of ordinary skill in the art appreciates that cells will respond differently (i.e., display different properties) based upon the materials placed in contact with those cells. Therefore, one of ordinary skill in the art would have no reasonable expectation that a polymeric material could substitute for ceramic materials to produce similar results as those obtained with ceramic materials.

In support of such a statement applicants provided with the previously submitted Request for Continued Examination (filed on February 25, 2008) a scientific publication (Kim et al, Biomaterials 27 (2006) p 1399-1409) demonstrating that a polymer by itself induces a minimal amount of *in vitro* osteoblast growth, alkaline phosphatase activity, and calcium deposition (all indicators of bone growth) compared to a nano ceramic (hydroxyapatite, "HA") composite when place in contact with cells *in vitro* (see Fig. 4 of Kim et al). Similar results were obtained upon implantation *in vivo* (see Figs. 6-8, and the text at page 1406, second column lines 5-7). Furthermore, the authors report that the composites presenting a higher exposure to the nano ceramic materials performed the best (see Figs. 4 and 8). Accordingly, this paper specifically addresses the failure of polymeric materials to substitute for ceramic materials, and thus supports the more general known principle that cells will respond in a highly variable and unpredictable way when contacted with a novel material relative to another tested material. Therefore, given the understanding of how cells respond to contact with different materials, the results reported in the '347 patent would not provide a reasonable expectation of success for duplicating the desirable results reported in the '347 patent when using polymeric materials instead of ceramic materials.

The Examiner contends that one of ordinary skill in the art would have been motivated to optimize the specific surface roughness of the implant, thus leading to the presently claimed composition. However, even if applicants accept that statement, the '347 patent only discloses modified ceramic surfaces and is devoid of any suggestion regarding the modification of any polymer component that is also present in the composition. The presently claimed invention requires a nanostructured polymeric material as an element of the composition. The '347 patent simply fails to consider or suggest that a polymer surface could be modified to display nano-sized surface features. As noted above one of ordinary skill in the art would not have a reasonable expectation of success duplicating the results obtained for nanostructured ceramic materials when using polymeric materials. The results obtained by applicants using polymeric materials that were prepared to display nano-sized surface features, and a surface roughness of about 50 nm or greater are surprising and unexpected. Such properties are the hallmark of non-obviousness.

The discovery of a new effective range is nonobvious when the results obtained using the new range are unexpectedly good. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). As disclosed in the present specification, and the Declaration by Dr. Webster (submitted with the 11/27/07 response and providing further experimental data), polymeric surfaces displaying surface features having dimensions less than 100 nm display unexpected

properties relative to the properties displayed by polymeric compositions having submicron or larger surface features. When an applicant demonstrates substantially improved results and states that the results were unexpected, this should suffice to establish unexpected results in the absence of evidence to the contrary. *In re Soni*, 54 F3d 746 (Fed. Cir. 1995). The existence of novel or superior unexpected properties, undisclosed by the prior art, weighs heavily in favor of a conclusion that the claimed composition is not obvious. *Air Products and Chemicals, Inc. v. Chas S. Tanner Co.*, 219 USPQ 223, 231 (SC 1983); *In re Chapp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987). Applicants have discovered the surprising result that polymeric compositions that display surface features having a dimension of less than 100 nm have dramatically improved desirable properties relative to polymer surfaces displaying submicron surface features. There was simply no reasonable expectation that polymeric materials would exhibit such properties prior to applicants' invention.

On page 6 of the Office Action the Examiner notes that an assertion of unexpected results requires a comparison with the closest prior art. Applicants respectfully submit that the primary reference (the Webster '347 patent) discloses composites comprising conventional polymeric materials which typically comprise micron sized or larger surface features. Applicants have shown that polymeric materials having micron or submicron surfaces perform equivalently, but polymeric materials that display nano-sized surfaces of 100 nm or less demonstrate surprising beneficial properties. Accordingly, applicants respectfully submit the data presented with the Declaration by Dr. Webster (submitted with the 11/27/07 response) compares a distinguishing element of the present invention with the most relevant element of the closest prior art reference. Therefore, applicants believe the Declaration by Dr. Webster (submitted with the 11/27/07 response and providing further experimental data) is relevant in further establishing the patentability of the claimed invention over the closest cited prior art.

The closest prior art reference (the '347 patent) simply fails to teach or suggest a composition comprising a polymeric material displaying nano-sized surface features. While the '347 patent discloses that polymeric materials can be included as a component of their compositions there is no teaching or suggestion that such polymeric material could be modified to display both nano-sized surface features and a surface roughness of 50 nm or greater. Repeatedly, throughout the specification of the '347 patent the only reference to nanostructured or nanophase material is in regards to ceramic materials. Furthermore, the '347 patent only provides a method of preparing nanostructured ceramics, and the disclosed

methodology is not applicable for preparing nanostructured polymeric material. Thus the '347 patent, in addition to its failure to teach or suggest the desirability of compositions comprising polymeric materials that display nano-sized surface features, also fails to enable the preparation of polymeric materials that display nano-sized surface features. Therefore, applicants respectfully submit that the invention of claims 1-5, 7-19 and 33-42 is patentably distinct over the teachings of the Webster '347 patent.

The Examiner makes several statements that "the instant claim language is open". However, the current claims still require an element (a polymeric material displaying nano-sized surface features) that is not taught or suggested by the prior art. Therefore, even though additional components can be included in applicants' claimed composition the claims will not read on compositions that fail to include a polymeric material that displays nano-sized surface features. Contrary to the Examiner's assertion on page 6, lines 2-6, the mere combination of polymeric and ceramic materials does not meet the claim language, because applicants claimed composition specifically requires the polymeric material to display nano-sized surface features, as opposed to "conventional" materials as defined in the '347 patent.

Furthermore, applicants note that claim 37 specifically excludes the presence of ceramic materials in the presently claimed invention. All compositions disclosed in the '347 patent comprise a ceramic component (i.e., alumina, titania or hydroxyapatite). The '347 patent fails to teach or suggest an implant that lacks the ceramic supporting structure. There is simply no suggestion in the '347 patent that an implant lacking such material could be prepared and have the requisite strength required for the uses disclosed in the present application. On page 7 of the Office Action the Examiner noted that claim 37 has been withdrawn from the rejection under 35 USC 103, and during the telephonic interview on October 10, 2008, the Examiner noted that claim 37 should not have been included with claims 1-5, 7-19, 33-36 and 38-42 in the rejection under 35 USC 103.

Applicants respectfully submit that the '347 patent fails to teach or suggest the present invention and applicants respectfully request the withdrawal of the rejection of claims 1-5, 7-19 and 33-42 as being obvious over the teachings of Webster (US Patent No. 6,270,347).

The Examiner states that claim 2 is rejected because the use of the phrase "about 50 nm", for example, allows for an unspecified range above and below the reference value. Applicants have amended claim 2 to remove the term "about" from the claim. Claim 4 stands rejected because employment of product by process language fails to further distinguish a

composition of matter. However, claim 4 is believed to be patentable because it depends from a patentable claim.

Claims 1-5 and 7-12 stand provisionally rejected based on nonstatutory obviousness-type double patenting as being unpatentable over claims 1, and 7-20 of co-pending Application No. 10/362,148. In addition, claims 1-5, 7-12 and 18 stand provisionally rejected as being unpatentable over claims 1-11 of co-pending Application No. 10/793,721. In accordance with MPEP 804 (see page 800-17 of the 2005 edition) applicants respectfully request that these rejections be held in abeyance until subject matter is allowed in one of the three identified co-pending applications.

Claim 37 stands rejected under 35 USC 112, second paragraph for indefiniteness. In particular the Examiner contends that the use of "about" in conjunction with "consisting of" transitional language is improper. Applicants respectfully traverse this rejection. However, in an effort to advance the prosecution of the present application, applicants have amended claim 37 to render the objection moot. Claim 37 as amended is believed to fully comply with 35 USC 112 and applicants respectfully request the withdrawal of that rejection.

The foregoing claim amendments and remarks are believed to fully respond to the Examiner's rejections, and the claims are believed to be allowable over the cited prior art. If any further discussion of this matter would speed prosecution of this application, the Examiner is invited to call the undersigned at (434) 220-2866.

Respectfully submitted,



John P. Breen  
Registration No. 38,833  
Attorney for Applicants

(317) 261-7940  
Indianapolis, Indiana 46204